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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,700	03/13/2002	Edwin L. Madison	24745-1613	4309

24961 7590 05/23/2003

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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,700	MADISON ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-116* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-19, 50-55, 59-61 and 65-72 drawn to a MTSP7 polypeptide-like protease or catalytic domain thereof, as well as conjugates and solid supports comprising same, and to a first method of use of a MTSP7 polypeptide-like protease in a method for identifying a compound capable of modulating the proteolytic activity of a MTSP7 polypeptide-like protease, classified, *inter alia*, in class 435, subclass 226.

Group II, claims 20-36 and 38-42 drawn, and 62-64 drawn in part, to a first method of making the product utilizing a nucleic acid encoding a MTSP7 or catalytic domain thereof and vectors and host cells comprising said nucleic acid and solid supports comprising same, classified, *inter alia*, in class 536, subclass 23.2.

Group III, claim 37, drawn to a second product, a transgenic animal, sustaining a deletion or inactivating mutation of protease-encoding gene, classified in class 800, subclass 8.

Group IV, claims 43 and 44, drawn to a nucleic acid molecule that is antisense to a portion of a protease-encoding gene, classified in class 536, subclass 24.5.

Group V, claim 45 and claims 62-64 in part, drawn to an oligonucleotide portion of a protease-encoding gene and to a solid support comprising same, classified in class 536, subclass 24.31.

Group VI, claims 46-49, drawn to an antibody that specifically binds to a MTSP7 polypeptide-like protease, classified in class 530, subclass 387.1.

Group VII, claims 56-58, drawn to a composition comprising an inhibitor of a MTSP7 polypeptide-like protease together with either an anti-tumor or an anti-angiogenic agent, classified in class 514, subclass 1.

Group VIII, claims 73-78, drawn to a method of using a MTSP7 polypeptide-like protease in identifying a compound capable of specifically binding to a MTSP7 polypeptide-like protease, classified in class 435, subclass 23.

Group IX, claims 79-82, drawn to a method of using a MTSP7 polypeptide-like protease zymogen for identifying a compound capable of activating the zymogen form of a MTSP7 polypeptide-like protease, classified in class 435, subclass 7.9.

Group X, claims 83-94, drawn to method of use of an inhibitor of the activity of a MTSP7 polypeptide-like protease, or activation of its zymogen, in treating or preventing neoplastic diseases including tumor initiation, growth or progression, or a malignant or pre-malignant conditions, classified in class 514, subclass 2.

Group XI, claims 95-98, drawn to a method of use of a MTSP7 polypeptide-like protease for identifying a compound that binds preferentially either to a single-chain or to a two-chain form of a MTSP7 polypeptide-like protease, classified in class 435, subclass 7.6.

Group XII, claims 99-104, drawn to a method of use of an unspecified product in detecting a neoplastic disease, classified in class 435, subclass 7.23.

Group XIII, claims 105-107, drawn to a method of use of an unspecified product in diagnosing the presence of a pre-malignant lesion, or a malignancy, or another pathological condition, classified in class 435, subclass 7.21.

Group XIV, claims 108-116, drawn to a method of use of an unspecified product in a method for monitoring tumor progress or therapeutic effectiveness, classified in class 436, subclass 86.

Inventions of Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Inventions of Group I and Groups III-VII, X, and XII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Groups I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, a method for identifying a compound capable of modulating the proteolytic activity of a MTSP7 polypeptide-like protease.

Inventions of Groups I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, a method for identifying a compound capable of modulating the proteolytic activity of a MTSP7 polypeptide-like protease.

Inventions of Groups I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as

claimed can be used in a materially different process of using that product, a method for identifying a compound capable of modulating the proteolytic activity of a MTSP7 polypeptide-like protease.

Inventions of Groups II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination may employ codons other than codons present in a native MTSP7 protease-encoding DNA sequence yet still serve in a recombinant method of making the native protease. The subcombination, which must have the codons present in a native MTSP7 protease-encoding DNA sequence in order to be useful, has separate utility such as use as a probe or primer.

Inventions of Group II and Groups III, IV, and VI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group III and Groups IV-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group IV and Groups V-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group V and Groups VI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group VI and Groups VII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group VII and Groups VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group VIII and Groups IX-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, or different effects.

Inventions of Group IX and Groups X-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, or different effects.

Inventions of Group X and Groups XI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group XI and Groups XII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group XII and Groups XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Inventions of Groups XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Ms. Stephanie L. Seidman on May 22, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct fax phone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
May 22, 2003